K130750

5 510(k) Summary

General Information

JUL 2 2 2013

Date Compiled	March 15, 2013
Classification	Class II, 21 CFR § 870.1425, Programmable Diagnostic Computer, Product Code DQK
Trade Name	Rhythmia Mapping System
Model Number	The Rhythmia Mapping System is comprised of several components, see form 3514 Section F for complete details. The model numbers of the main components include: M004RH1000 0 through M004RH4400 0.
Submitter	Rhythmia Medical, Inc. 111 South Bedford Street, Suite 205 Burlington, MA 01803
Contact	Leon Amariglio Rhythmia Medical, Inc. 111 S Bedford St. Suite 205 Burlington, MA 01803 Phone: 617-591-9191 Fax: 617-449-9513

Indications for Use

The Rhythmia Mapping System and accessories are indicated for catheter based atrial and ventricular mapping. The mapping system allows real-time visualization of intra-cardiac catheters as well as display of cardiac maps in a number of different formats. The acquired patient signals, including body surface ECG and intra-cardiac electrograms, may also be recorded and displayed on the system's display screen.

Predicate Device

CARTO 3 EP Navigation System (K072202)

Manufactured by Biosense Webster, Inc.

EnSite System Model EE3000 (K070902)

Manufactured by St. Jude Medical

Device Description

The Rhythmia Mapping System and accessories are designed for electroanatomical mapping and is able to simultaneously acquire data from multiple electrodes. The Rhythmia Mapping System tracks catheters inside the heart in order to visualize their location and construct geometric shells. The Rhythmia Mapping System is also capable of using intra-cardiac location and electrical information to display electroanatomical maps - electrical activity information on the constructed geometry. Such electrical information can be visualized in 3D in color. The Rhythmia Mapping System can display various types of electroanatomical maps including geometrical shell only, activation maps, voltage maps and fractionation maps.

Testing

In vitro testing was performed on the Rhythmia Mapping System to assure reliable design and performance. The bench tests performed by the company included software verification and validation and hardware verification and validation. The test results demonstrate that the Rhythmia Mapping System meets the requirements in the applicable standards and specifications, and is substantially equivalent to the legally marketed predicate device.

In vivo testing

Design validation of the system was performed in a GLP animal study. The Rhythmia Mapping System was used in a swine model to determine the system's ability to record and display intracardiac electrograms, share intracardiac and ECG signal with recording system, route stimulator signal, create geometrical shells, create activation maps, create voltage maps, accurately track the position of the Rhythmia Mapping Catheter, and accurately track the position of third party catheters. The Rhythmia Mapping System worked as intended and there were no safety issues identified.

Clinical experience

A clinical evaluation was performed outside the US using the Rhythmia Mapping System. Thirty-three (33) subjects were included in the studies using the Rhythmia Mapping System. There were no adverse events related to the Rhythmia Mapping System, and the System performed as intended.

Summary of Substantial Equivalence

Rhythmia Medical believes the Rhythmia Mapping System and accessories are substantially equivalent to the predicate products. The indications for use, intended use, product function, design and materials used, are either identical or substantially equivalent to existing legally marketed predicate products.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-002

July 22, 2013

Rhythmia Medical, Inc.
C/O Mr. Leon Amariglio
111 South Bedford St Suite 205
Burlington, MA 01803 US

Re: K130750
Trade/Device Name: Rhythmia mapping system
Regulation Number: 21 CFR 870.1425
Regulation Name: Programmable Diagnostic Computer
Regulatory Class: Class II
Product Code: DQK
Dated: June 7, 2013
Received: June 10, 2013

Dear Mr. Leon Amariglio:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act

or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Owen P. Faris -S

for Bram D. Zuckerman, Ph.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K130750

4 Indications for Use Statement

510(k) Number (if known):	This application
Device Name:	Rhythmia Mapping System
Indications for Use:	The Rhythmia Mapping System and accessories are indicated for catheter based atrial and ventricular mapping. The mapping system allows real-time visualization of intra-cardiac catheters as well as display of cardiac maps in a number of different formats. The acquired patient signals, including body surface ECG and intra-cardiac electrograms, may also be recorded and displayed on the system's display screen.

Prescription Use _X_ AND/OR Over-The-Counter Use_____

(Per 21 CFR 801 Subpart D) (Per 21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Digitally signed by Owen P. Faris -S
Date: 2013.07.22 14:19:01 -04'00'